Paper No. 49

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID PORUBEK,
ANIL M. KUMAR, and
CHARLES R. BREDL

Appeal No. 2001-1101
Application No. 08/932,834

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1, 2, 4, 6, 7, 9, 10, 12 through 16, 18 through 21, and 23 through 27, which are all of the claims remaining in the application.

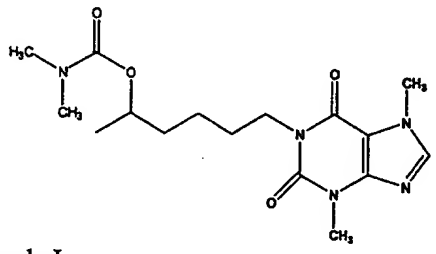
The Invention

The invention relates to compounds that form the hydroxy-substituted zanthine, lisofylline, in vivo. These compounds, or prodrugs, are said to possess a primary,

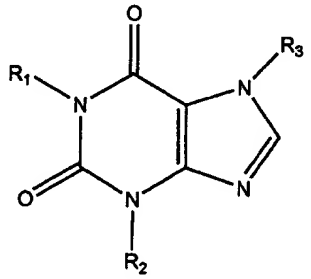
characteristic benefit, viz., selective enantiomeric stability coupled with varying resistance to hydrolysis (Specification, paragraph bridging pages 5 and 6).

Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. A compound having the following structure:

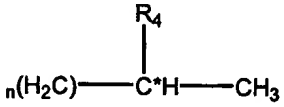


or a structure according to formula I:



I

wherein R_1 has the formula II:



R_2 and R_3 are independently $C_{(1-12)}$ alkyl, optionally, R_2 having one or two nonadjacent carbon atoms of the $C_{(1-12)}$ alkyl being replaced by an oxygen atom; and wherein:

C* is a chiral carbon atom;

n is four;

R_4 is a naturally occurring amino acid or a carbohydrate-moiety attached by an oxygen atom to the chiral carbon atom C* by an ester linkage, -O-X-$(R_5)_m$; m being two or three, depending on valence, and X being selected from the group consisting of C, P or S; wherein one R_5 is =O and any other R_5 is a member independently selected from Group Q,

said carbohydrate moiety is selected from the group consisting of glucosyl, glucosidyl, maltosyl, glucopyranosidyl, glyceraldehydyl, erythrosyl, arabinosyl, ribolucosyl, fructosyl, erythritolyl, xylosyl, lyxosyl, allosyl, altrosyl, mannosyl, mannosidyl, gulosyl, idosyl, galactosyl and talosyl, and

Group Q consists of:

hydroxyl group;

substituted or unsubstituted $C_{(3-10)}$ alkyl, $C_{(2-10)}$ alkenyl, $C_{(2-10)}$ alkynyl, $C_{(1-10)}$ alkoxyl, $C_{(1-10)}$ oxoalkyl, $C_{(1-10)}$ carboxyalkyl, $C_{(1-10)}$ hydroxyalkyl, or substituted $C_{(1-2)}$ alkyl group;

-OR_6, R_6 being a substituted or unsubstituted $C_{(1-10)}$ alkyl, $C_{(2-10)}$ alkenyl, $C_{(2-10)}$ alkynyl, or $C_{(1-10)}$ oxoalkyl;

substituted or unsubstituted heterocylic group, attached to X through an atom within the ring, having one or two rings, each ring containing from four to seven atoms, wherein the heteroatom(s) of said heterocyclic group is 1 or 2 nitrogens; and

substituted or unsubstituted carbocyclic group that is attached to X through a carbon atom within a ring, having one or two rings, each ring containing four to seven atoms, wherein the substituents of said substituted carbocyclic group are selected from the group consisting of amino, $C_{(2-6)}$ alkenyl, $C_{(1-6)}$ alkyl, $C_{(1-6)}$ alkoxyl, $C_{(1-6)}$ hydroxyalkyl, hydroxyl, $C_{(1-6)}$ oxoalkyl, azido, cyano, $C_{(2-6)}$ mono- or di-haloalkyl, isocyano, isothiocyano, imino, a chlorine atom, a bromine atom, a fluorine atom and an oxygen atom.

Prior Art

In rejecting the appealed claims under 35 U.S.C. § 112, first and second paragraphs, the examiner does not rely on any prior art references (Examiner's Answer, Paper No. 43, Section (9)).

The Rejections

Claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27 stand rejected under 35 U.S.C. § 112, second paragraph, as not particularly pointing out and distinctly claiming the subject matter which applicants regard as their invention.

Claims 1, 2, 4, 6, 7, 9, 10, 12 through 16, 18 through 21, and 23 through 27 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which does not adequately teach any person skilled in the art how to use the claimed invention.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 through 10 and all of the claims on appeal; (2) the amended Appeal Brief (Paper No. 42); (3) the Examiner's Answer (Paper No. 43); and (4) the Paradise Declaration, filed under the provisions of 37 CFR § 1.132, executed June 17, 1999 (Paper No. 32).

On consideration of the record, including the above-listed materials, we affirm the examiner's rejection of claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27 under 35 U.S.C. § 112, second paragraph. We reverse the rejection of claim 14 under 35 U.S.C. § 112, first paragraph, and we do not reach the rejection of the remaining claims under that statutory provision.

Preliminary Matter

As a preliminary matter, we refer to section VII of the amended Appeal Brief entitled "GROUPING OF THE CLAIMS." Applicants ask that we consider two groups of claims separately, stating that "[c]ompound claims 1, 2, 4, 6, 7, 9, 10, and 12-14 are patentable regardless of whether pharmaceutical composition claims 15, 18-21 and 23-27 are patentable" (Paper No. 42, Section VII). That section of the Appeal Brief, however, makes little sense. First, applicants have not set forth a grouping of claims "for each ground of rejection which appellant contests" as required by 37 CFR § 1.192(c)(7) (1999). Second, applicants have omitted claim 16 from their grouping of claims. Third, applicants' statement to the contrary, notwithstanding, claims 20, 21, and 23 through 27 are drawn to compounds, not pharmaceutical compositions.

Nonetheless, applicants' error in grouping claims for purposes of this appeal may be viewed as "harmless error" in view of our disposition of each ground of rejection discussed infra.

35 U.S.C. § 112, Second Paragraph

As stated in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989): "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." In the

Answer (Paper No. 43), the examiner points to several aspects of the appealed claims which are incorrect, indefinite, ambiguous, or simply make no sense. We shall not belabor the record on this point, because we agree substantially with the examiner's analysis. For reasons ably set forth by the examiner in the Answer, we affirm the rejection of claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27 under 35 U.S.C. § 112, second paragraph, as not particularly pointing out and distinctly claiming the subject matter which applicants regard as their invention.

We here note that the examiner rejected all claims in the application, except claim 14, under 35 U.S.C. § 112, second paragraph. Our affirmance of that rejection constitutes a disposition of the appeal with respect to all claims except claim 14.

35 U.S.C. § 112, First Paragraph

The remaining issue is whether the examiner erred in rejecting all of the appealed claims under 35 U.S.C. § 112, first paragraph, as based on a specification which does not adequately teach any person skilled in the art how to use the claimed invention. Under the circumstances, however, we shall not reach the merits of the "how to use" rejection with respect to claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27. Again, those claims are indefinite within the meaning of 35 U.S.C. § 112, second paragraph; they are not precise, clear, correct, and unambiguous. We think it imperative to understand the metes and bounds of the claims before proceeding to a resolution of an examiner's rejection under 35 U.S.C. § 112, first paragraph. Cf. In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962)(Before deciding a

rejection under 35 U.S.C. § 103, "it is essential to know what the claims do in fact cover").

We now turn to a consideration of claim 14, cast in Markush format and reciting, in the alternative, 15 prodrugs of lisofylline. The examiner argues that it would require undue experimentation "to get lisofylline to actually work" (Paper No. 43, page 7, line 7). It follows, according to the examiner, that applicants' specification does not teach any person skilled in the art how to use the prodrugs recited in claim 14 without undue experimentation. In other words, the examiner's argument centers on lisofylline. If persons skilled in the art know how to use lisofylline, within the meaning of 35 U.S.C. § 112, first paragraph, the examiner would not deny that such persons would also know how to use the 15 prodrugs recited in claim 14.

It is uncontroverted on this record that "lisofylline is the subject [of] FDA-sanctioned Phase II and Phase III clinical trials." See the Paradise Declaration, filed under the provisions of 37 CFR § 1.132, executed June 17, 1999, paragraph 3 and Appendix E. As stated in In re Brana, 51 F.3d 1560, 1568, 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995), in the context of a PTO rejection under 35 U.S.C. § 112, first paragraph,

> Were we to require Phase II testing [FDA-sanctioned Phase II trials] in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

A fortiori, that lisofylline is the subject of FDA-sanctioned Phase II and Phase III clinical trials establishes, on this record, that any person skilled in the art knows how to use

lisofylline within the meaning of 35 U.S.C. § 112, first paragraph. As stated in the Paradise Declaration, paragraph 3., "[m]erely getting such trials approved require [sic] substantial indications of therapeutic efficacy." Accordingly, the premise of the examiner's rejection is incorrect and the rejection cannot be sustained.

Further, the examiner argues that applicants' specification does not provide useful daily dosage information (Paper No. 43, page 10, last full paragraph; and paragraph bridging pages 10 and 11). We would agree that there is room for improvement in applicants' description of a dosage regimen at page 9, first full paragraph of the specification. That passage, standing alone, is somewhat unclear. This does not, however, end the inquiry. Rather, the specification must be considered in its entirety taking into account the level of skill in the art. The following passage appears in the specification, page 9, second full paragraph:

> While dosage values will vary, therapeutic compounds of the invention may be administered to a human subject requiring such treatment as an effective oral dose of about 50 mg to about 5000 mg per day, depending upon the weight of the patient. For any particular subject, specific dosage regimens should be adjusted to the individual's need and to the professional judgment of the person administering or supervising the administration of the inventive compounds.

In our judgment, the above-quoted passage adequately conveys to any person skilled in the art useful daily dosage information for the claimed compounds.

The examiner's rejection of claim 14 under 35 U.S.C. § 112, first paragraph, is reversed.

Conclusion

In conclusion, for reasons set forth in the body of this opinion, we sustain the examiner's rejection of claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27 under 35 U.S.C. § 112, second paragraph.

We do not reach the merits of the "how to use" rejection under 35 U.S.C. § 112, first paragraph, with respect to claims 1, 2, 4, 6, 7, 9, 10, 12, 13, 15, 16, 18 through 21, and 23 through 27.

We do not sustain the examiner's rejection of claim 14 under 35 U.S.C. § 112, first paragraph.

The examiner's decision is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Sherman D. Winters)
Administrative Patent Judge)
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William F. Smith) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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Lora M. Green) INTERFERENCES
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